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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,261	07/24/2003	Joel D. Oxman	56464US003	9585

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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/626,261	<b>Applicant(s)</b> OXMAN ET AL.	
	<b>Examiner</b> Lezah W. Roberts	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15-19, 21-23, 26-29, 32-35, 40-46 and 48-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 15-19, 21, 22 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 26-29, 32-35, 40-46 and 48-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>A and B</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

This office action is in response to the amendment filed August 12, 2006. All previous rejections have been withdrawn unless indicated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Independent claims 1, 21, 57 and 58 are amended to add the limitation that the polymerizable component does not comprise an ionic group. In the response to the election of species requirement filed February 7, 2006, Applicant elected PEGDMA, TEGDMA and IA:ITA:IEM as polymerizable component. It is the Examiner's understanding that the elected species is no longer within the scope of the above amended independent or its dependent claims because of the itaconic acid is an ionic group. Therefore independent claims 1, 21, 57 and 58 and their dependent claims 2, 4-10, 15-19 and 59 have been withdrawn from consideration. Claims 3 and 22 are also withdrawn from consideration as being drawn to a non-elected species. (Note also: the incorporation of ionic group appears to be new matter. Applicant seems to have support for "pendant ionic groups" not simply all "ionic groups".)

Claims 23, 26-29, 32-35, 40-46 and 48-56 will be further examined on the merits.

## ***Claims***

### **Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 recites the limitation "claim 30" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 30 has been cancelled.

### **Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)**

Claims 1-7, 15-19, 21-30, 34-35, 40, 44-46, 48-49 and 53-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Joshi et al. (US 5,252,318). The rejection is maintained in regards to claims 23, 26-29, 34-35, 40, 44-46, 48-49 and 53-56. Claims 1-7, 15-19, 21-22, 36 and 57 have been withdrawn from consideration. Claims 24-25 and 30-31 have been cancelled.

Applicant argues the claims recite a thermally responsive composition including a polymerizable component. Joshi et al. fails to disclose a thermally responsive composition including a polymerizable component. The Examiner has not indicated any specific disclosure in Joshi et al. that supports the above-cited assertion. Thus further clarification of the support for the rejection is respectfully requested in the next Official

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Communication. Applicants disagree with the Examiner's assertion and submit that it would be clear to one of ordinary skill in the art that the crosslinking agent is added to the monomers used to make the exemplary pH-triggered gelling polymers, not to a thermally responsive composition. This argument is not persuasive.

The invention of Joshi et al. provide aqueous compositions that reversibly gel in response to substantially simultaneous variations in at least two physical parameters such as temperature, pH, or ionic strength. What is more, the compositions of the present invention can be tailored to exhibit a specific sol-gel transition over predetermined temperature and pH ranges to make the compositions particularly well suited for use as drop-instillable aqueous wetting agents and drug delivery systems, as well as for use as injectable sustained release drug delivery systems (col. 2, line 66 – col. 3, line 8). Therefore the compositions are both pH-triggered gelling polymers and thermally responsive compositions. Therefore the crosslinking agents as disclosed by the reference (col. 3, lines 51-66) would be in a thermally responsive composition.

**Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

1) Claims 23, 26-29, 32-35, 40-46 and 48-51 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bromberg et al. (US 5,939,485).

Bloomberg et al. teach responsive polymer networks and methods of their use. The networks comprise a structural polymer made from monomers and a responsive polymer in an aqueous solution. The responsive polymers that may be used include polyoxyalkylene polymers and copolymers, such as a block copolymer of

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polyoxyethylene and polyoxypropylene (col. 7, lines 25-53), which encompasses claim 35. The structural polymer is made from monomers, which include acrylic acid, methacrylic acid and ethacrylic acid (col. 7, lines 34-67). Adding an initiator such as free radical initiators, or UV or gamma radiation initiators polymerizes the monomers, which encompasses claims 40-42. The two components are incorporated into the compositions at concentrations ranging from 0.01 to 20 % (col. 15, lines 59-67).

Exemplary drugs or therapeutic delivery systems which may be administered using the aqueous responsive polymer network compositions of the invention include mucosal therapies, such as esophageal, buccal oral (it can be concluded that all types of tissue found in the oral cavity are included in this phrase encompassing hard and soft tissue), vaginal, and urological applications; topical therapies, such as wound care, skin care and teat dips; and intravenous/subcutaneous therapies, such as intramuscular, intrabone (e.g., joints), spinal and subcutaneous therapies, tissue supplementation, adhesion prevention and parenteral drug delivery (col. 11, lines 21-33), which encompasses claims 44 and 56. Drugs that may be delivered by the invention include lidocaine (col. 14, line 59), which encompasses claims 45-46. The compositions are reversible and viscosity increases at least by 5-fold, which encompasses claims 26 and 53-54. In the case of claims 27-28, if the temperature is lowered the gelling process will be reversed. The reference differs from the instant claims insofar as it does not disclose the compositions are applied to the hard tissue of the teeth but does disclose the compositions are applied to the oral cavity.

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It would be obvious to one of ordinary skill in the art to have used the systems of the reference to apply compositions to the hard surfaces of the oral cavity motivated by the desire to use a vehicle that is suitable for using in the oral cavity and because the hard tissues are a part of the oral cavity.

2) Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bromberg et al. (US 5,939,485) in view of Murray (4,659,572).

The primary reference is disclosed above in the anticipation section subsection 3. The reference differs from the instant claim insofar as it does not teach mixing the disclosed compositions by static mixing.

Murray teaches compositions that have a delayed setting. They mix the components of the compositions by using static mixing. In-line static mixing devices are currently on the market. Devices of this type are ideally suited for dispensing delayed set liquid materials. One such device includes twin syringes, one of which is filled with the solution to be set, and the other is filled with the setting agent. Simultaneous extrusion of the two liquids through a disposable static mixing tube associated with the device is an effective and very convenient method of mixing the component liquids. This method also remedies degradation of the compositions when the two components are mixed together and stored. The mixing unit allows to mix the components before use (col. 15, lines 1-12). The reference differs from the instant claims insofar as it does not teach a method wherein the monomer unit of one component is polymerized.

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It would have been obvious to one of ordinary skill in the art to have used the static mixing procedure in the method of the primary reference motivated by the desire to mix the components of the compositions with efficiency, simultaneously and convenience as disclosed by the secondary reference.

Claims 23, 26-29, 32-35, 40-46 and 48-56 are rejected.

Claims 1-10, 15-19, 21-22 and 57-59 have been withdrawn.

Claims 24-25 and 30-31 are cancelled.

No claims allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts  
Patent Examiner  
Art Unit 1614



Frederick Krass  
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